REMARKS

In the Office Action dated August 25, 2004, claims 33, 34 and 36 are pending and under examination. Claim 36 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 20-26, 38-44 and 47-55 of copending Application No. 09/436,164. Claim 36 is rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Claim 36 is further rejected under 35 U.S.C. §102(b) as allegedly anticipated by Thomson et al. (Science 282: 1145-1147, 1998). Claim 36 is rejected under 35 U.S.C. §102(e) as allegedly anticipated by Thomson (U.S. Patent No. 6,200,806). Claims 33 and 34 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Vajta et al. (*Acta Vet Scan* 1997 or *Mol Reprod Dev* 1998).

This Response addresses each of the Examiner's rejections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Claim 36 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 20-26, 38-44 and 47-55 of copending Application No. 09/436,164. The Examiner contends that although the conflicting claims are not identical, they are not patentably distinct from each other. Specifically, the Examiner states that claim 36 encompasses any described embryonic stem cell, and is directed to a cell referenced in the examples. The Examiner also states that the examples in the specification describe culturing human embryonic stem cells and differentiating the cells in culture into defined lineages. Therefore, the Examiner concludes that the conflicting claims are not patentably distinct because the method of making and using a product (embryonic stem cells) are obvious in view of the product.

Applicants respectfully submit that in copending Application No. 09/436,164, the Examiner determined that the claims (including claim 36), which were drawn to a purified preparation of undifferentiated human embryonic stem cells and a method of isolating such cells, belonged to Group I. The Examiner also determined that Group I was separate and patentably distinct from Group II, drawn to a method of inducing somatic cell differentiation, a method of isolating the committed progenitor cell from a population of differentiated cells, and an isolated differentiated cell. See Restriction Requirement dated July 5, 2001 and the Office Action dated October 25, 2001. As a result, Applicants pursued the subject matter of Group II in the '164 application and eventually canceled non-elected claims including claim 36. The present application was filed as a divisional of the '164 application to pursue the non-elected subject matter, including claim 36. Applicants respectfully submit that it is erroneous, and certainly unfair to Applicant, for the Patent Office to require restriction in the '164 application, and is now asserting obviousness in the present application.

Applicants further respectfully submit that claims 20-26, 38-44 and 47-55 have been canceled in the '164 application, rendering the provisional rejection moot.

In view of the foregoing, it is respectfully submitted that the provisional double patenting rejection of claim 36 is overcome. Withdrawal of the rejection is therefore respectfully requested.

Claim 36 is rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Specifically, the Examiner contends that claim 36 fails to point out what is included or excluded by the claim language. The Examiner states that the claim appears to be drawn to a human embryonic stem cell line. The Examiner contends that there is no description of human embryonic stem cell lines in any of the examples provided in the specification, only a description of the propagation of isolated inner cell mass cells for several passages.

In response, claim 36 has been amended to refer specifically to Example 6 of the specification, which describes human embryonic stem cell lines, particularly, hES-1. The preparation of human embryonic stem cell lines, including hES-1, is also described in Example 1. It is respectfully submitted that claim 36, as presently amended, is not indefinite. Withdrawal of the rejection of claim 36 under 35 U.S.C. §112, second paragraph, is therefore respectfully requested.

Claim 36 is further rejected under 35 U.S.C. §102(b) as allegedly anticipated by Thomson et al. (Science 282: 1145-1147, 1998).

The Examiner contends that Thomson et al. (Science) teach human pluripotent embryonic cell lines, H13, H14, and H7. According to the Examiner, Thomson et al. also teach that when the cell lines are injected into an immunodeficient mouse, the cell lines can differentiate into endoderm, mesoderm and ectoderm cell types. Further, the Examiner contends that Thomson et al. characterize the cell lines in culture and demonstrate that differentiation of the cells results in various cell types, including neuronal cells. Thomson et al. allegedly disclose several parameters that affect differentiation of the cell lines, including the feeder layer, the cell density, and various growth factors. Therefore, the Examiner concludes that in view of the breadth and lack of clarity of the claimed methodology, the teachings of Thomson et al. anticipate the method set forth in claim 36.

It is observed that claim 36 is drawn to a human embryonic cell line, not to any method. Therefore, it appears to Applicants that the Examiner considers Thomson et al. (Science) anticipate the claimed cell line, because it is the Examiner's position that the method of Thomson et al. would give rise to the cell line as claimed.

Applicants respectfully submit that claim 36 has been amended to refer to Example 6, which describes the cryopreservation method in connection to human ES cells. Applicants respectfully submit that Thomson et al. (Science) do not disclose cryopreservation of hES cells as described in Example 6 of the specification, or hES cells prepared by cryopreservation. Therefore, it is respectfully submitted that Thomson et al. (Science) do not teach the hES cells as presently claimed. Withdrawal of the rejection of claim 36 under 35 U.S.C. §102(b) based on Thomson et al. is therefore respectfully requested.

Claim 36 is rejected under 35 U.S.C. §102(e) as allegedly anticipated by Thomson (U.S. Patent No. 6,200,806). The Examiner's characterization of the '806 patent is essentially the same as that of Thomson et al. (Science).

Applicants respectfully submit that similar to Thomson et al. (Science), the '806 patent does not disclose cryopreservation of hES cells as described in Example 6 of the specification, or hES cells prepared by cryopreservation. Therefore, it is respectfully submitted that the '806 patent does not teach the hES cells as presently claimed. Withdrawal of the rejection of claim 36 under 35 U.S.C. §102(e) based on the '806 patent is therefore respectfully requested.

Claims 33 and 34 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Vajta et al. (*Acta Vet Scan* 1997) or Vajta et al. (*Mol Reprod Dev* 1998).

Claim 33 is drawn to a method of preserving a differentiated or undifferentiated cell by vitrification. Dependent claim 34 specifically indicates that the method is the Open Pulled Straw method of vitrification. The Examiner alleges that the specification does not specifically define the Open Pulled Straw method. The Examiner contends that Vajta et al. (1998) teach an Open Pulled Straw method for the vitrification of ova and embryos, which

represent differentiated and undifferentiated cell types. The Examiner also contends that Vajta et al. (1997) teaches an Open Pulled Straw method for cryopreserving morula, blastocysts and embryos of the pig. Therefore, the Examiner concludes that Vajta et al. (1997) and Vajta et al. (1998) both anticipate the claimed methods.

Applicants respectfully submit that claim 33 has been amended to recite "differentiated or undifferentiated *human* embryonic stem cells". Neither Vajta et al. (1997) nor Vajta et al. (1998) disclose vitrification of *human* ES cells. The teaching of Vajta et al. (1997) relates to pig embryos, and the teaching of Vajta et al. (1998) relates to bovine ova and embryos. Applicants submit that a rejection of a claim under 35 U.S.C. §102(b) requires that the prior art reference disclose every element of the claim. The absence from the reference of any claimed element negates anticipation. Kloster Speedsteel AB v Crucible Inc., 793 F.2d 1565, 1571, 230 USPQ 81, 84 (Fed. Cir. 1986). Therefore, it is respectfully submitted that claims 33-34, as presently recited, are not anticipated by the cited references.

Applicants further submit that it is not evident from Vajta et al. (1997) or Vajta et al. (1998) that human ES cells could be frozen and survive under the conditions disclosed therein in connection with embyros. Embryos are much larger and are more likely to survive a vitrification process than ES cells. Therefore, it is respectfully submitted that the claimed methods are not only novel, but also unobvious in light of the Vajta et al. references.

Accordingly, it is respectfully submitted that the rejection of claims 33-34 under 35 U.S.C. §102(b) based on Vajta et al. (1997) or Vajta et al. (1998) is overcome. Withdrawal of the rejection is therefore respectfully requested.

In view of the foregoing amendment and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

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